

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78, and 83-86 are pending in the application, with claims 1, 46, 66, and 78 being the independent claims. Claims 1, 3, 16-18, 66, and 78 have been amended as suggested by the Examiner. Claim 41 was amended to correct the antecedent basis, and claim 85 was amended to correct a typographical error. These changes are believed to introduce no new matter, and their entry is respectfully requested.

This Amendment is being filed along with a request for continued examination. Therefore, entry of the amended claims is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objection to the Title

Applicants have amended the title as required by the Examiner. Applicants believe that the title is now clear and respectfully request reconsideration and removal of the objection.

Objection to the Abstract

Applicants have amended the abstract as requested by the Examiner. Applicants respectfully request reconsideration and removal of the objection.

Rejections under 35 U.S.C. § 112

Claims 16 and 18 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended claims 16 and 18 to depend from claim 1. Accordingly, the rejection has been rendered moot and Applicants respectfully request that the rejection be reconsidered and removed.

Other Matters

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78, and 83-86 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 164, 185, 189, 201, 202, 206, 207, 209, 210, 212, and 213 of copending U.S. Appl. No. 09/839,574 (the '574 application) in view of Dalglish (Cancer Surveys, 296:289-320 (1995)). Applicants respectfully traverse.

The pending claims in the '574 application recite administration of DNA and a salt, however what makes the pending claims in the present application patentably distinct over the '574 claims is that pending claims in the present application do not require the use of an auxiliary agent, such as a poloxamer or reverse poloxamer. Furthermore, the pending claims of this application are drawn to treatment methods

comprising administration of a DNA plasmid, where the plasmid expresses a cytokine in sufficient quantity to treat tumors at a site distal to the site of administration, which was surprising and unexpected.

In addition, Applicants respectfully assert that the combination of Dalglish is improper because Dalglish teaches delivery of a protein. Dalglish does not teach that the delivery of a DNA plasmid to muscle would allow for sufficient expression of a polypeptide to treat a tumor at a distal site. Therefore, Applicants respectfully submit that the claims of this application are patentably distinct and non-obvious from those pending in the '574 application and request that the rejection be reconsidered and removed.

Claims 1, 3-6, 16-18, 30-35, 38-41, 43, and 46-50 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 48, 52, 57, 59, 61, 72, 74, 76, 77, 79, 81, 82, and 84 of copending U.S. Appl. No. 09/588,655 (the '655 application) in view of Dalglish (Cancer Surveys, 296:289-320 (1995)). Applicants respectfully traverse.

As stated above, the currently pending claims are drawn to treatment methods comprising administration of a DNA plasmid to muscle, where the plasmid expresses a cytokine in a sufficient quantity to treat tumors at a site distal to the site of administration, which was surprising and unexpected. In contrast, the pending claims of the '655 application recite delivery of polynucleotides to heart tissue and expression of gene products encoded by the polynucleotides in the heart.

Additionally, as stated above, Applicants respectfully assert that the combination of Dalglish is improper because Dalglish teaches delivery of a protein. Dalglish does

not teach that the delivery of a DNA plasmid to muscle would allow for sufficient expression of a polypeptide to treat a tumor at a distal site. Therefore, Applicants respectfully submit that the claims of this application are patentably distinct and non-obvious from those pending in the '655 application and request that the rejection be reconsidered and removed.

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78, and 83-86 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the claims of copending U.S. Appl. No. 10/028,782 (the '782 application). Applicants respectfully traverse.

The pending claims of this application are drawn to delivery of DNA which is distinct from the currently pending claims of the '782 application which are limited to delivery of RNA. Therefore, Applicants respectfully assert that the claims of this application are patentably distinct from those of the '782 application and request that the rejection be reconsidered and removed.

Conclusion

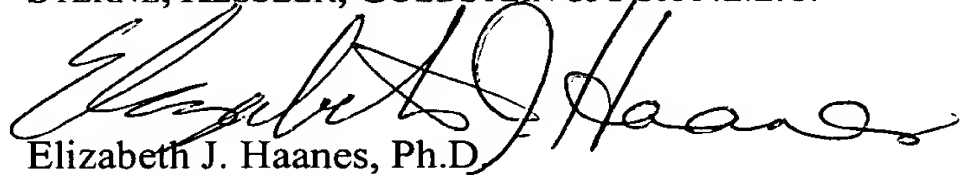
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in cursive script, appearing to read "Elizabeth J. Haanes".

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Date: Feb. 27, 2004

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